UPDATE: FTC: Generic Biologics Won't Erode Competition

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WASHINGTON (Dow Jones)--Members of a House subcommittee struggled Thursday to balance a desire to encourage development of less-expensive, generic biologic drugs while still providing incentives to develop innovative new medicines.

In a debate that crossed party lines, members of a House Energy and Commerce subcommittee sparred over whether to create a faster approval process for generic biologics. The complex medicines are made from proteins and living matter, unlike traditional chemical drugs. A commissioner from the Federal Trade Commission testified that speeding up the approval process would benefit consumers.

"Drugs that are not affordable offer no consolation and a drug not invented offers no cure," said Rep. Tim Murphy, R-Pa.

FTC Commissioner Pamela Jones Harbour said that the nature of the biologics market would prevent generic versions from significantly cutting into the profits of original manufacturers. Biotech companies - including Genentech, Amgen Inc. (AMGN) and AstraZeneca Inc. (AZN.N) - are among the major players in the biologics market.

Rather, generics would most likely battle competitively with the original drugs, she said, citing a report released Wednesday by the commission. The report supported giving the FDA authority to approve generic biologic drugs as a way to reduce costs for the expensive biotechnology medicines.

"Follow-on entry will not radically erode the pioneer's market share," Jones Harbour said.

Because biologic drugs are so complex, they will remain expensive to manufacture, even in generic form. The commission expects that only two or three generic biologic manufacturers will compete in each drug product. By contrast, with traditional pharmaceuticals, manufacturers may create eight or more new generic products that may drive the price down by as much as 80%.

And because it is currently impossible to prove that a generic biologic is identical to the original drug -- only similarity can be shown -- customers may not immediately jump for the generic version, Jones Harbour said. The commission predicted that the first biologics to hit the market would retain 70% to 90% of the market share and prices would dip only between 10% and 30%, still a significant consumer savings.

"This means that a pioneer firm will continue to reap substantial profits for years, even after entry by a [generic] biologic," Jones Harbour said.

Wednesday's report also urged Congress to create a faster approval process for generic biologic drugs. It proposed giving the Food and Drug Administration the authority to approve generic biologics without the full gamut of clinical studies. The commission took a strong stance against allowing the initial biologic manufacturers to enjoy exclusive rights to sell its drug for 12 to 14 years. The report also discouraged "pay-for-delay" settlements, in which the companies manufacturing the original drug pay would-be makers of generic drugs to delay introducing their cheaper product.

The committee is weighing two proposed bills, one introduced by Reps. Anna Eshoo, D-Calif.; Jay Inslee, D-Wash.; and Joe Barton, R-Texas, that would grant manufacturers 12 years of exclusivity before generic biologics could hit the market. A competing bill introduced by Rep. Henry Waxman, D-Calif., sets a shorter five-year exclusive period.

Many lawmakers representing districts with a biotechnology presence said they were concerned that removing a period of exclusivity could discourage the companies from investing in the development of new drugs.

"I am sincerely torn right now on this issue," said Rep. Zack Space, D-Ohio. "I have a child who suffers from a disease and is alive today because of biologics. I understand the need to foster innovation."

Because biologic drugs are so expensive, introducing generic biologic drugs could save money for both consumers and the government, through lower Medicare reimbursements. The FTC report estimated that a year of treatment with the biologic drug Herceptin, used to treat breast cancer, costs $48,000. In 2007, according to the commission, $40.3 billion of the $286.5 billion Americans spent on prescription medicine was for biologic drugs.

Congress passed similar legislation in 1984 with the Hatch-Waxman Act, which encouraged companies to produce generic versions of traditional pharmaceuticals.